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April 2, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 98N-0826: Food Labeling: Use on Dietary Supplements of Health Claims Based on Authoritative Statements

TO WHOM IT MAY CONCERN:

The American Society of Health-System Pharmacists (ASHP) is pleased to provide comments on the Food and Drug Administration's (FDA) proposed rule permitting the use of health claims based on authoritative statements on dietary supplements that was published in the *Federal Register* on January 21, 1999. ASHP is the 30,000-member national professional association representing pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care organizations, and other components of health care systems.

At its Annual Meeting in June 1998, ASHP adopted the following policy, entitled "*Regulation of complementary and alternative substances*":

To support Food and Drug Administration (FDA) regulatory authority over complementary and alternative substances for which claims -- even indirect and general claims -- are made by manufacturers or distributors about their usefulness in preventing and treating disease; further,

To support the principle that complementary and alternative substances not having proven efficacy but having no appreciable toxicity should be allowed to be marketed (but not as drugs or biologics) with labeling that clearly states their lack of proven efficacy....

ASHP developed this policy stance because it recognized that in addition to substances already classified as drugs or biologics, there are many other substances (identified by the FDA as "dietary supplements, but which ASHP has identified in its policy statement as "complimentary and alternative substances") that are used by consumers with pharmacologic intent. There is abundant literature and promotional information about these products, but ASHP's members are concerned that much of this information is not scientifically based.

Obviously, any substance used with pharmacologic intent has a potential for therapeutic benefit as well as harm. Given the origins of many dietary supplements, the variety of suppliers, and the lack of regulatory production standards, it is logical to anticipate that the products have

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inconsistent ingredients, uncertain contaminants, and variable concentrations. Due to these circumstances, as well as the vigorous promotion and sizable economic market of these products, and the fact that many patients entering care in health systems are increasingly found to be users of such products, ASHP believes that there is a substantial potential for eventual public harm.

ASHP agrees with the FDA that it is in the best interests of the public that conventional foods and dietary supplements should be subject to the same standards and procedures in regard to the use of health claims based on authoritative statements. Therefore, ASHP supports the proposal.

One question that ASHP has is where will the data for these claims be housed, and will the data be readily available to consumers and health care professionals? ASHP adopted another policy at its June 1998 Annual Meeting. Entitled "*Pharmacists as a source of information about dietary supplements and alternative or complementary substances*," that policy is:

To support the principle that pharmacists should be informed about dietary supplements and alternative or complementary substances, and capable of providing sound advice to patients about their use; further

To support the principle that pharmacists and pharmacies should foster public confidence that they are accessible sources of available authoritative information about dietary supplements and alternative or complementary substances; further

To support the principle that pharmacists' recommendations about the use of dietary supplements and alternative or complementary substances should be based on scientific evidence of safety and efficacy.

The January 21, 1999, proposed rule will assist pharmacists by providing them with important information about the source and accuracy of health claims on dietary supplements.

ASHP appreciates the opportunity to respond to the FDA's request for comments on its proposal to allow health claims based on authoritative statements to appear on dietary supplement labels. Feel free to contact me if you have any questions regarding our comments.

Sincerely,



Gary C. Stein, Ph.D.
Director, Federal Regulatory Affairs